REMARKS

Claims 1, 3, 4, 6-17, and 21-24 are pending in the application, with Claims 11-17 and 21-24 under examination and Claims 1, 3, 4, 6-10, and 18-20 withdrawn. With the entry of this Response, Claims 1, 6, 9, 11-17, and 21-24 are amended. The amendments to the claims are supported by the application as originally filed and do not introduce new matter. For reference purposes, all citations to the pending Application refer to U.S. Patent Application Publication No. 2004/0096410.

REJECTION OF CLAIMS 11-17 AND 22-24 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner rejected Claims 11-17 and 22-24 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. The Examiner stated that "support for the [the limitation 'pressure sensitive adhesive-free' and 'in an amount effective to treat'] is lacking and the addition of said limitation is new matter." In the currently amended claims, these phrases are no longer present. Applicants respectfully request the Examiner to withdraw this rejection.

REJECTION OF CLAIMS 11-17 AND 22-24 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner rejected Claims 11-17 and 22-24 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner stated that "the specification, while enabled for the creation of a diffusion gradient between the claimed composition and nail structures, as set forth in example 3, 6, and 7 of the instant specification, is not enabled for the creation of a diffusion gradient between the claimed composition and all dermal structures, as claimed . . . [as] one of ordinary skill in the art would be faced with an undue experimental burden in attempting to practice the invention commensurate in scope with the claims." Applicants respectfully traverse this rejection.

Undue experimentation would not be required to practice the currently claimed invention. According to the court in In Re Wands, "a considerable amount of experimentation is permissible if it is merely routine, or if the specification in question provides a reasonable

amount of guidance with respect to the direction in which the experimentation should proceed."[1] The Examiner acknowledged that the present specification is "enabled for the creation of a diffusion gradient between the claimed composition and nail structures." Applicants respectfully submit that the creation of a diffusion gradient between the present composition and the listed dermal structures would not require undue experimentation. Applicants respectfully submit that the present specification provides a reasonable amount of guidance regarding establishment of a diffusion gradient. Establishment of a diffusion gradient between the present composition and a particular dermal surface may require routine experimentation by a person having ordinary skill in the art. A requirement for establishing a diffusion gradient between the presently claimed composition and a dermal surface is that the currently claimed composition have a greater concentration of moisture, and optionally, greater concentration of at least one active agent, than the dermal surface. Determination of the moisture condition of the dermal structure and providing a greater concentration of moisture in the claimed composition may require experimentation, but such experimentation is not out of the realm of routine experimentation. The creation of a diffusion gradient between the claimed composition and such dermal structures would not require undue experimentation. Therefore, "creation of a diffusion gradient between the claimed composition and the cited dermal structures" is enabled by the present specification. Applicants respectfully request the Examiner to withdraw this rejection.

REJECTION OF CLAIMS 11-17 UNDER 35 U.S.C. § 102(b)

The Examiner rejected Claims 11-17 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,270,358 to Asmus (hereinafter, "Asmus"). The Examiner stated that Asmus "discloses a transdermal composition comprising . . . a hydrogel of instant claim 11; the active agent of instant claim 11; the humectant (e.g. glycerol) of instant claim 11; the moisture content of instant claim 11; [and] the organic acid of instant claim 11 . . . ." Applicant respectfully traverses this rejection.

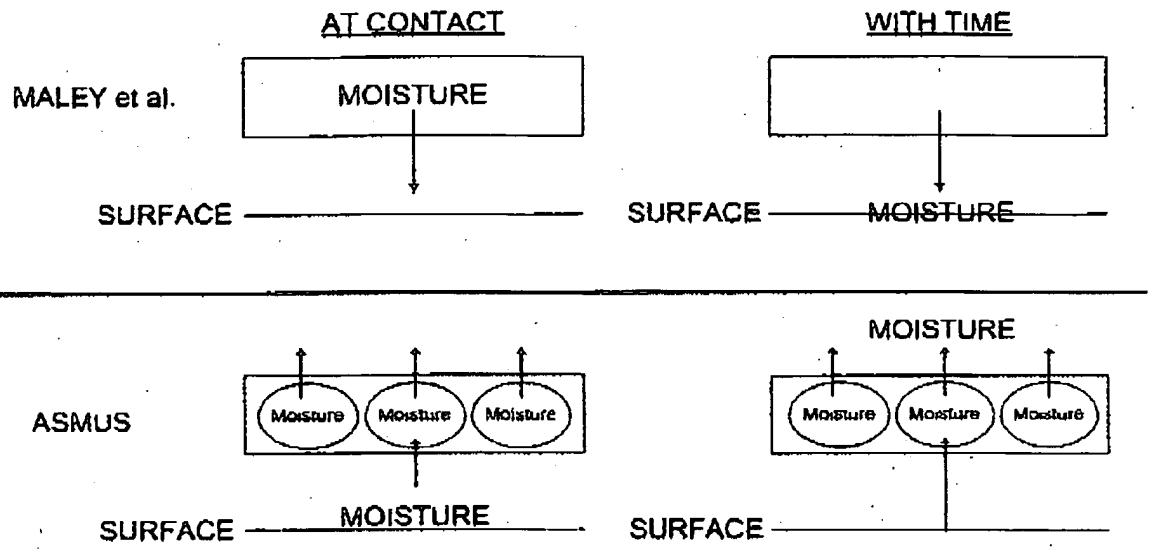
A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Applicants respectfully

[1] 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir 1988) (*citing* Ex parte Forman, 230 U.S.P.Q 546, 547 Bd. Pat. App. & Int. 1986))

submit that Asmus does not set forth each and every element of the currently amended claims. Therefore, Asmus does not anticipate the presently claimed invention.

Asmus teaches a "gel-adhesive composite . . . compris[ing] a two phase system." (Asmus, Col 4. lines 46-47). Asmus teaches a "gel adhesive composite [that] requires at least three components: (1) a pressure sensitive adhesive as a continuous matrix; and in the dispersed gel, (2) a hydrocolloid and (3) a swelling agent for the hydrocolloid." (Asmus, Col. 2, lines 42-45). In the composition of Asmus, the hydrocolloid "gel particles dispersed in the continuous adhesive matrix provide the means by which moisture at the skin is continuously removed by diffusion of moisture through the gel adhesive layer." (Asmus, Col 18, lines 18-22). The hydrocolloid gel particles with a swelling agent "continuously dry an otherwise wet environment by the transmission of moisture from the skin or the skin opening while the adhesive matrix maintains adhesion." (Asmus, Col. 18, lines 42-45).

The composition of Asmus does not anticipate the presently claimed invention because there is no teaching in Asmus of a composition that establishes a diffusion gradient wherein moisture is provided from the composition to a surface. Asmus teaches a hydrophobic adhesive matrix having particles of a hydrocolloid gel dispersed within the matrix that have a high moisture vapor rate wherein moisture is moved from the contacted surface to the outer surrounding environment. (Asmus, Col. 16, lines 36-38; *see also* Figure 1). The composition of Asmus has a "high moisture vapor transmission rate . . . [that] facilitates removal of moisture or other fluid from the area where the composite is adhered." (Asmus, Col. 3, lines 45-48). Asmus discloses a moisture removal composition, not a moisture delivering composition. (*See*, Figure below). Considering that Asmus only discloses a moisture removal composition, Asmus cannot teach a composition such as the currently claimed invention which delivers moisture from the composition to the contacted surface. Applicants respectfully submit that Asmus does not disclose each and every element of the currently claimed invention. Therefore, Asmus cannot anticipate the presently claimed invention. Applicants respectfully request the Examiner to withdraw this rejection.



REJECTION OF CLAIMS 21-24 UNDER 35 U.S.C. § 103(a)

Claims 21-24 were rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,270,358 to Asmus (hereinafter, "Asmus"). The Examiner stated that "Asmus discloses a transdermal composition comprising a hydrogel [and] . . . provides utility for skin adhesive applications. While Asmus does not explicitly teach the percentages of instant claims 21-23, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation . . . ." Applicants traverse this rejection.

A claimed invention is patentable when the prior art fails to teach the claimed subject matter as a whole. 35 U.S.C. § 103(a); *see also* MPEP § 2141. Applicants respectfully submit that Asmus does not teach or suggest all of the claim features as a whole, for example, there is no teaching in Asmus of a composition having a diffusion gradient wherein moisture moves from the composition to the contacted site. Asmus teaches a "gel adhesive composite [that] requires at least three components: (1) a pressure sensitive adhesive as a continuous matrix; and in the dispersed gel, (2) a hydrocolloid and (3) a swelling agent for the hydrocolloid." (Asmus, Col. 2, lines 42-45). In the composition of Asmus, the hydrocolloid "gel particles dispersed in the continuous adhesive matrix provide the means by which moisture at the skin is continuously

removed by diffusion of moisture through the gel adhesive layer." (Asmus, Col 18, lines 18-22). The hydrocolloid gel particles with a swelling agent "continuously dry an otherwise wet environment by the transmission of moisture from the skin or the skin opening while the adhesive matrix maintains adhesion." (Asmus, Col. 18, lines 42-45).

The composition of Asmus does not render the presently claimed invention obvious because Asmus teaches an adhesive matrix having particles of a hydrocolloid gel dispersed within the matrix that removes moisture from a surface. The composition of Asmus has a "high moisture vapor transmission rate . . . [that] facilitates removal of moisture or other fluid from the area where the composite is adhered." (Asmus, Col. 3, lines 45-48). The composition of Asmus discloses a moisture removal composition, not a moisture delivering composition, as is illustrated in the Figure above. Considering that Asmus discloses a composition that functions as a moisture removal composition, Asmus cannot teach or suggest a composition that comprises a moisture delivery system.

Given the difference between the directionality of the diffusion gradients in Asmus and the presently claimed invention, a person having ordinary skill in the art would not have a reasonable expectation of success in adapting the teachings of Asmus to result in the presently claimed invention. The composition of Asmus removes moisture from the skin to the composition and beyond. The other components of the Asmus composition do not alter this fundamental aspect of moisture removal, and thus do not provide a teaching or suggestion of components of Applicants' currently claimed invention.

Applicants respectfully submit that Asmus does teach or suggest the presently claimed invention as a whole. Applicants also submit that there is no reasonable expectation of success in adapting the teachings of Asmus to result in the presently claimed invention. For at least these reasons, Applicants submit that Asmus does not teach or suggest the currently claimed invention. Therefore, Applicants respectfully request the Examiner to withdraw this rejection.

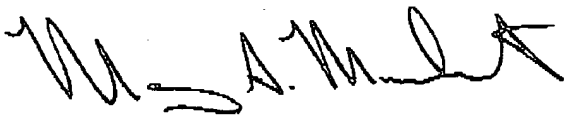
CONCLUSION

The foregoing is a complete response to the Action dated September 7, 2007. Applicants respectfully submit that the pending claims are patentable. Early and favorable consideration is solicited.

The Commissioner is hereby authorized to charge the two month extension of time fee of $230, and any other fees that may be required, or credit any overpayment, to Deposit Account No. 20-1507.

If the Examiner believes there are other issues that can be resolved by a telephone interview, or that there are any informalities that remain in the application which may be corrected by the Examiner's amendment, a telephone call to the undersigned attorney at (404) 885-3652 is respectfully solicited.

Respectfully submitted,



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